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August 30, 2000

Dockets Management Branch (HFA-305)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: FDA Docket No. 98N-0331 (CDRH Draft Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997)

To Whom It May Concern:

CITECH is an Accredited Person within the context of the third party program for review of eligible 510(k) submissions. We participated in the Pilot Program in 1996, and have completed our review of 13 third party submissions. We welcome the proposed expansion of the Accredited Person program to include third party review of submissions for which there are no specific guidance documents. However, we are concerned that some of the requirements for third party review of these documents will not further the stated objective of increasing industry participation and thereby lightening FDA's load.

As a general comment, we believe that much of the caution evident in the subject document is unwarranted, given the fact that FDA reserves to itself the final review and decision making; it is also contrary to FDA's stated "Least Burdensome" principles. The Accredited Persons have demonstrated the basic competence and other ethical prerequisites needed to conduct effective reviews of 510(k) submissions. This, plus FDA's ability to more carefully review any submission from a third party over which there is concern before rendering a final determination of equivalence, should constitute sufficient safeguards to prevent clearing a device that is not Substantially Equivalent.

We believe that Accredited Persons should be given special status with respect to access to certain internal FDA documents, if the third party review program is to realize its full potential. For example, when an Accredited Person undertakes a review for a device that does not have a specific guidance document, the Accredited Person should be given prompt access to internal FDA review memos (purged, if necessary) for previous submissions for the same device. The rationale for this special status is that Accredited

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5200 Butler Pike
Plymouth Meeting, PA 19462-1298
Phone: (610) 825-6700
Fax: (610) 834-1275
E-mail: info@citechtest.com

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Persons are already being judged as FDA employees with respect to conflict of interest; we see no valid reason to withhold from them information that FDA would use to train its own employees.

The following specific comments are presented in order of appearance in the text. In these comments, we use the term "third party" synonymously with "Accredited Person."

Sec. II.B, Purpose and Nature of the Program

The Purpose and Nature of the Program is the first instance in which mention is made that Class II devices that require clinical data (in the premarket notification) are ineligible for third party review. There is a need to define "clinical data." For example, noninvasive blood pressure measurement systems have been eligible for third party review, despite the fact that the recognized standard, ANSI/AAMI SP10, calls for clinical data. Specifically, SP10 requires comparison of blood pressure measurements from the subject device and those of either auscultatory or direct measurement for a range of human subjects with various arm sizes and blood pressures.

The same section places certain restrictions on third party review of submissions for which there is no specific guidance document; we believe that some of these restrictions are unnecessary and will severely discourage the use of third parties for these devices. We have no argument with the requirement that the third party have completed at least three 510(k) reviews for which there are guidance documents (or for Class I devices); this experience is reasonable to confirm the third party's basic ability to conduct reviews. However, the proposed guidance requires that the third party also have completed review of at least one 510(k) that is in the same or similar medical specialty area as the device that the third party intends to review. We believe that this restriction is unnecessarily burdensome. Third parties must already be accredited for each specialty or device that they wish to review. We assume that, to grant this accreditation, FDA examines the background of specific third party individuals. Such examination should be sufficient to judge competence in a particular specialty, whether or not there is a specific guidance available for the device in question. Furthermore, there are some medical specialties (e.g., anesthesiology, ENT) in which very few devices are currently eligible for third party review. Given the current rate of reviews by third parties, it could be some time before a third party reviews a submission in these specialty areas. Finally, using anesthesiology as

an example, there is only one device—nebulizers—currently eligible for third party review. The list being proposed includes such anesthesiology devices as gas machines for anesthesia (21 CFR 868.5160) and electrical peripheral nerve stimulators (21 CFR 868.2775). We do not see how reviewing a nebulizer submission relates to a third party's ability to review one for these other devices.

There are general procedures to be followed when reviewing a 510(k) for which there is no specific guidance. These procedures can be addressed during training sessions for Accredited Persons, similar to those conducted by FDA at the start of both the Pilot Program in 1996 and the current Accredited Person program in 1998. We would not object to making attendance at this training mandatory for third parties that wished to review submissions for the new devices. It would also be useful for FDA to repeat these training programs periodically, to accommodate new Accredited Persons or new employees at existing ones.

The June 12 draft requires that the third party contact ODE to identify certain issues and criteria on submissions without specific guidance, and then submit a summary of these discussions to ODE. There is no indication of what ODE does with this information and when. While it is not explicitly stated, the implication is that ODE may withhold permission for the third party to conduct that review. If this is so, it represents a burdensome obstacle and delay to expansion of the third party program, and the need for these discussions has not been demonstrated. As stated earlier, FDA already requires submission of personnel qualifications in each specialty area; these should be sufficient to allow that third party to review devices being added to the eligibility list for that specialty. Furthermore, if the intent of this requirement for prior contact and discussion is that ODE may withhold permission from the third party, the criteria for such action should be clearly defined.

Sec. II.B, Qualifications of Accredited Persons; 3) Prevention of Conflicts of Interest

In paragraphs (a), (b), and (d), the term "device" is used interchangeably with "medical device." We believe this is an editorial error. We do not believe it can be demonstrated that a potential conflict would exist if the Accredited Person, for example, had a relationship with a manufacturer or distributor of devices that were not medical in any way.

Sec. II.B, Identification of an Accredited Person

The second paragraph of this section states that the repeated use of the same Accredited Person by a manufacturer may call into question the independence or objectivity of that third party; it also indicates that FDA might implement procedures to restrict a manufacturer's ability to do this. We believe that one of the reasons for the limited use of third parties by industry is that the third parties have much less experience than FDA in reviewing 510(k) submissions. Of those that have used third parties, manufacturers often use the same third party repeatedly, precisely because the working relationship and experience with the company's products help expedite subsequent reviews. The integrity of a test house (e.g., Underwriters Laboratories) is never called into question because it does extensive work for one company (e.g., General Electric); we see no reason to question the independence of a third party based solely on the volume of contracts with a single company. We believe that this portion of the paragraph should be deleted.

Sec. II.B, Document Processing by FDA

Continuing present practice, FDA proposes to send the decision letter to the third party, not the submitter. We believe that this is counterproductive for a Substantially Equivalent decision letter, because it adds to the time for the submitter—the one with the greatest stake in the decision—to learn of the final action. As further evidence of the need to change the current practice, CITECH recently received a request from FDA's Freedom of Information Office to redact a 510(k) for which we had been the third party reviewer several years earlier. Since we had not had any contact with the submitter in the intervening time, it was only by chance that we located the appropriate individual at that firm and had him indicate his response to me, which I forwarded to FDA. We propose that a Substantially Equivalent decision letter be sent directly to the manufacturer, with a copy to the third party.

Thank you for this opportunity to present our comments on the subject Guidance. We look forward to expansion of the program in the near future.

Sincerely,

Robert Mosenkis
President

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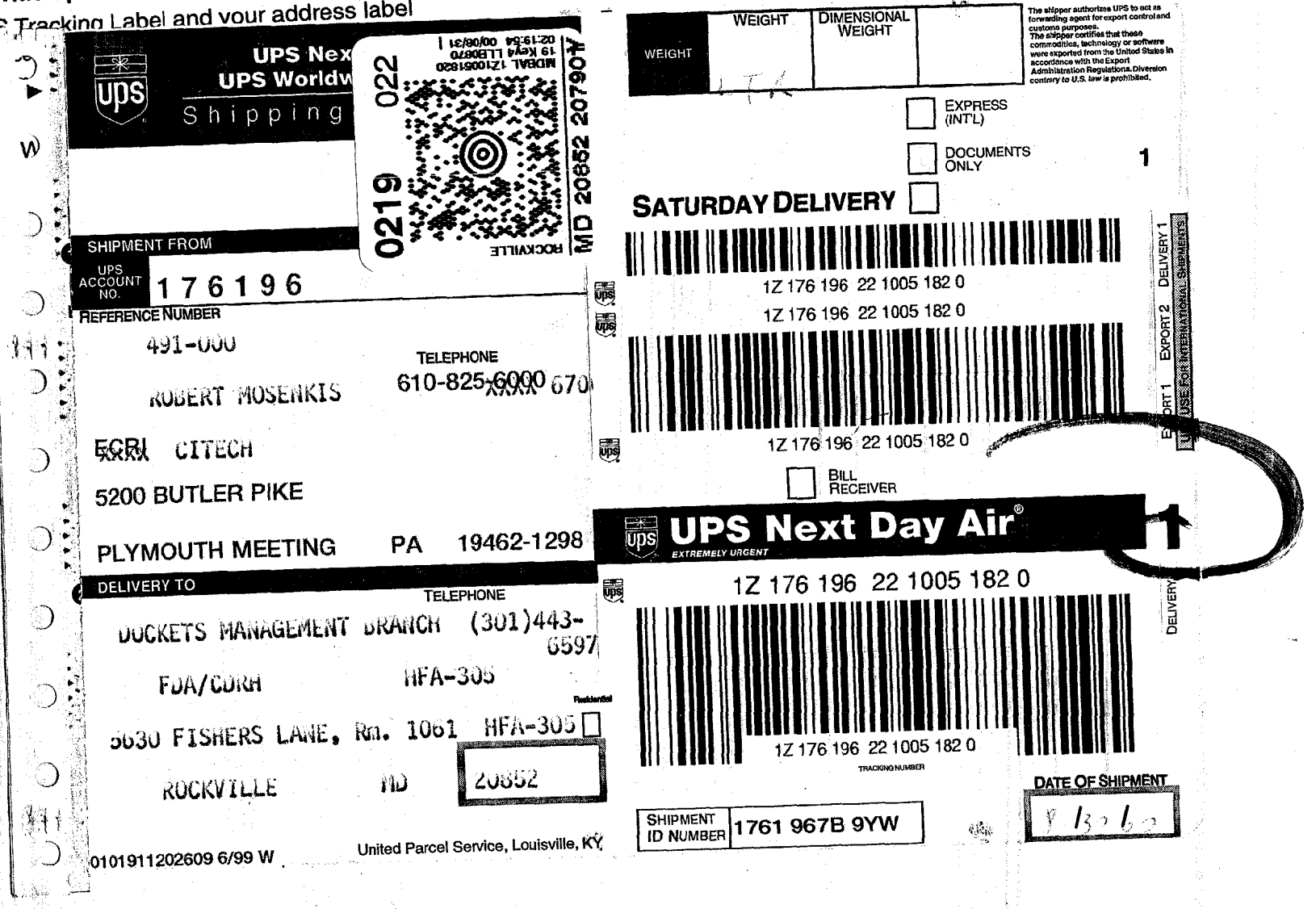

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